Sodium Chloride Injection, 0.9 percent, 1000 mL, Flexible Container: Recall - Brass Particulates

[Posted 04/01/2013]

AUDIENCE: Risk Manager, Pharmacy

ISSUE: Hospira, Inc. notified healthcare professional of a voluntary nationwide user-level recall of one lot of 0.9% Sodium Chloride Injection, USP, 1000 mL, Flexible Container, NDC 0409-7983-09. This action is due to one confirmed customer report where brass particulate was identified in the primary container in the form of several small grey/brown particles. The affected lot number is 25-037-JT (the lot number may be followed by a -01 or -90), with an expiration date of January 1, 2015. Hospira is investigating to determine the root cause.

The brass particulate was identified as containing copper, zinc and lead. If administered, solution containing brass particulate may result in occlusion of small blood vessels. In a worst-case scenario, copper toxicity may potentially result in hemolysis and liver toxicity, including hepatic necrosis which may be fatal.

BACKGROUND: The product is used as a source of water and electrolytes and is packaged in a 1000 mL flexible container. The affected lot was distributed nationwide between January 2013 and March 2013 to wholesalers/distributors, hospitals and pharmacies.

RECOMMENDATION: Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-480-2853 between the hours of 8am to 5pm EST, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[1]
- Download form[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[03/29/2013 - Press Release[3] - Hospira, Inc]

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